

Cover page

Title: Comparing Nasal Suction Devices in Children with Bronchiolitis: A Pilot Study

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Section Aa: Title & PIA1. Main Title

COMPARING NASAL SUCTION DEVICES IN CHILDREN WITH BRONCHIOLITIS: A PILOT STUDY.

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Organization: FRIDABABY LLC

A6a. Institution(s) where work will be performed:

TCH: Texas Children's Hospital

A6b. Research conducted outside of the United States:

Country:

Facility/Institution:

Contact/Investigator:

Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?

No

Section B: Exempt RequestB. Exempt From IRB Review

Not Applicable

Section C: Background Information

Bronchiolitis is a viral illness and a common cause for admission to the hospital. Most patients with bronchiolitis are managed at home. The indications of hospitalization are poor feeding, respiratory distress with and without hypoxia. The hospital is a common destination of patients with bronchiolitis. Patients are admitted to the hospital for respiratory monitoring, suctioning and poor oral intake. The management of bronchiolitis is mostly supportive which includes frequent feedings, nasal suctioning, intravenous fluids and oxygen if necessary. Several studies have looked at barriers to discharge from the hospital. The factors identified were hypoxia, frequent deep nasal suctioning, parental and physician discomfort, respiratory distress, and poor feeding. In one study, 50% of parents of patients with bronchiolitis were reluctant to go home. The role of nasal suctioning has not been studied extensively. The AAP practice guidelines on bronchiolitis do not support routine deep suctioning of the posterior pharynx or larynx. It does, however support suctioning of nares to provide temporary relief of nasal congestion. At our institution, nasal suctioning is widely practiced.

Bronchiolitis is associated with increased mucus production. Patients with mild bronchiolitis are able to be managed by suctioning alone. The patients admitted to the hospital get frequent nasal suctioning by a suction device. The rationale behind nasal suctioning is that young infants are nose breathers and nasal secretions impair their ability to breathe and feed. Nasal suctioning overcomes upper airway obstruction and diminishes work of breathing. However, frequent suctioning can cause local trauma, rebound swelling and increase length of stay. Since suctioning causes temporary relief, suctioning lapses of more than 4 hours potentially can increase length of stay. The role of the suctioning device in the management of patients with bronchiolitis has not been studied. Since the suction controlled nasal aspirator was first developed by Benincaso et al. in 1973 several nasal

aspirators and suction devices have been developed. Suctioning can be done by bulb suction devices, nasal aspirators or suction catheters connected to pressure devices.⁶ The potential complications include hemodynamic instability, mucosal trauma, pneumothorax, prolonged coughing during the procedure, bleeding and cross infection.⁶ In Italy, a prospective observational study was conducted on a nasal aspirator Narhinel and its safety, efficacy and parental satisfaction were studied. The nasal aspirator showed improvement in sleep, feeding and improvement in respiration. There were some reported instances of minor nasal bleeds. The purpose of our study is to compare an over the counter nasal aspirator by the brand name of NoseFrida to the suction device used in the hospital- the NeoSucker. The purpose of our study is to determine the safety, efficacy, length of stay and parental satisfaction of the Nosefrida in comparison to suction devices used in the hospital setting in patients with bronchiolitis. References: 1. Nagakumar P, Doull L. Current therapy for bronchiolitis. *Archives Diseases of Childhood* 2012; 97:827-830. 2. Crocetti MT, Barone MA, Amin DD, Walker AR. Pediatric Observation Status Beds on an Inpatient Unit: An Integrated Care Model. *Pediatric Emergency Care* 2004; 20(1); 17-21. 3. Diagnosis and Management of Bronchiolitis. Subcommittee on Diagnosis and Management of Bronchiolitis. *Pediatrics* 2006; 118; 1774. 4. Mussman GM, Parker MW, Statile A, Sucharew H, Brady PW. Suctioning and Length of Stay in Infants Hospitalized with Bronchiolitis. *JAMA Pediatrics* 2013; E1-E8. 5. Benincaso FV and Smith MHD. A suction-controlled nasal aspirator for collection of nasopharyngeal secretions. *The Journal of Pediatrics* Feb 1973; 82(2): 297-299. 6. Moore T. Suctioning techniques for the removal of respiratory secretions. *Nursing Standard* Feb 2003; 18(9): 47-53. 7. Casati M, Picca M, Marinello R, Quartarone G. Safety of use, efficacy and degree of parental satisfaction with the nasal aspirator Narhinel in the treatment of nasal congestion in babies. *Minerva Pediatrics* Aug 2007; 59(4): 315-25. 8. Wai AKC, Kwok WO, Chan MS, Graham CA and Rainer TH. Patients' perceptions of nasopharyngeal aspiration in the emergency department of a teaching hospital in Hong Kong. *Emergency Medicine Journal* 2007; 24:35-36. 9. Hampton, E., & Abramson, E. (2017). Less is more: Evidence-based management of bronchiolitis. *Pediatric Annals*, 46(7), e252-256. doi:<http://dx.doi.org.ezproxyhost.library.tmc.edu/10.3928/19382359-20170620-02>

Section D: Purpose and Objectives

The purpose of our study is to compare the NoseFrida with the neosucker nasal suction device used in the hospital setting for patients with bronchiolitis. If this device (Nose Frida) is comparable to the neosucker device, patients with bronchiolitis can be managed at home and potentially avoid hospital admission. The objectives of this study are to answer the following research questions: 1) Is there a difference in the length of stay for patients treated with the NoseFrida compared to the NeoSucker? 2) What is the level of satisfaction of the parents of patients treated with the NoseFrida? 3) Does the proportion of patients readmitted within 48 hours differ for NoseFrida compared to the NeoSucker? 4) Do complication rates differ for NoseFrida compared to the NeoSucker?

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:

Both

Age:

Infant/Toddler (0-36 mos)

Ethnicity:

All Ethnicities

Primary Language:

English, Spanish

Groups to be recruited will include:

Patients

Which if any of the following vulnerable populations will be recruited as subjects?

Children

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

The protection of human subject is important in this study. Patient confidentiality will be protected and maintained during the study. No personal identifiers will be used on the database. Confidentiality of information will be maintained by using identifier numbers only on study records. Chart review will only be done within the facility. The patient identity will not be recorded and the investigators will protect the confidentiality of the records. No potential risk or discomfort is anticipated to the individual patients as the device being used is a nasal aspirator which is over the counter product recommended for suction of babies with nasal congestion.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

Yes

Section F: Design/ProcedureF1. Design

Select one category that most adequately describes your research:

c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

The study will be performed at TCH Main Campus inpatient units. This study is a pilot study. A sample size of 150 has been calculated to provide a rough estimate of how many patients need to be enrolled for the study. The target population for this study is patients with bronchiolitis admitted to the hospital for poor feeding, respiratory distress, or for frequent nasal suctioning. Patients who meet inclusion criteria will be randomized into 2 groups (NoseFrida group and NeoSucker group which is the standard of care). The potential subjects may or may not be the clinical patients of the PI and co-investigators. The patients may be taken care by other physicians in the hospital setting. Block randomization will be used with a block size of four to ensure that a similar number of subjects are assigned to each device. The study statistician will generate the randomization sequence before study enrollment begins. Sequentially numbered sealed envelopes will contain the device to which the patient is randomized.

Inclusion Criteria:

Patients above the age of 2 months and post-gestational age to 44 weeks and less than or equal to 2 years with signs and symptoms of bronchiolitis and clinical respiratory score (CRS) of less than or equal to 4 admitted to the hospital. The patients will have a principle diagnosis of Bronchiolitis.

Exclusion Criteria:

Patients to be excluded from the study are as follows: Age less than post-gestational age 44 weeks, CRS greater than 4, associated hypoxemia requiring high flow oxygen management, already using NoseFrida at home, diagnosis of chronic lung disease, oro-facial abnormalities, or hemodynamically significant congenital heart disease. Less than 1 year post-op ASD/VSD repair.

F2. Procedure

This study is a pilot study which will be performed on children with bronchiolitis admitted to the hospital medicine service. The potential subjects may or may not be the patients of the PI and co-investigators. Patients will be identified based on the inclusion criteria. Consent will be obtained from identified patients. A study packet (consent form, inclusion and exclusion criteria and data collection tool) will be then initiated and completed by the Research Coordinator. This study packet will remain with the patients chart until disposition, when they are to be collected and stored in a password protected computer. Upon enrollment, the study patients will be randomized to nasal suctioning by either the NoseFrida or the NeoSucker suction catheter device. The subject's participation in this research study will continue until discharged or moved to a higher level of care. The PLAN procedure in SAS version 9.3 (SAS Institute., Cary, NC) will be used to randomize subjects to one of the two devices. Block randomization will be used with a block size of four to ensure that a similar number of subjects are assigned to each device. The study statistician will generate the randomization sequence before study enrollment begins. Sequentially numbered sealed envelopes will contain the device to

which the patient is randomized. Only after the patient has been consented and enrolled into the study will the envelope be opened to reveal the device to which the patient has been randomized. For patients randomized to the NoseFrida, the Research Coordinator will provide a video demonstration of NoseFrida use and will give an instructional post card to the parent/guardian. Both video and postcard will be available in English or Spanish. Parents will then re-demonstrate appropriate use of the device. The NoseFrida has four components, the collection container, an interchangeable filter, flexible tubing and a mouth piece. The end of the collection device is placed on the patient's nostril, a tight seal is made via the vacuum created from suctioning of the mouth piece and secretions are easily aspirated. This device disassembles for quick disinfecting and cleaning. If at any time deep suctioning is necessary the nurse will perform as reflective of our current standard of care. If at any time overnight the patient requires nasopharyngeal suctioning and the parent/guardian are asleep, the nurse will suction with the NeoSucker (current standard of care). The NeoSucker is used for nasopharyngeal suctioning and requires a nurse/respiratory therapist. The NeoSucker is connected to the extension tubing leading to the wall suction canister. The NeoSucker is invasive, placed inside the child's nostril and secretions are then aspirated. We will review patient records following discharge from Texas Children's Hospital in order to determine return visits. Data will be collected on a data collection tool. A copy of which is attached to this IRB protocol. Once data points are collected, data will be stored in a computer which will be only be accessed by the Research Coordinator, PI and the co-investigators. Following completion of the database, statistical analysis will be performed.

Section G: Sample Size/Data AnalysisG1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 150 Worldwide: 150

Please indicate why you chose the sample size proposed:

This is a pilot study. A sample size has been calculated based on the average length of stay which is variable. One hundred and fifty subjects are expected to be enrolled during the study period which would yield 75 subjects randomized to each of the two suction devices. For the 136 patients in fiscal year 2016, the mean \pm standard deviation length of stay was 1.80 ± 1.29 days. Assuming the same standard deviation for the NeoSucker, the table below displays the sample sizes needed to achieve 80% statistical power to detect ($\alpha=0.05$) various mean length of stay values in the NoseFrida group.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Length of stay will be compared for the two devices using two one-sided t-test and parental satisfaction will be compared via the Wilcoxon Rank Sum test. The proportion of patients readmitted within 48 hours, the proportion requiring deep suctioning, gender, ethnicity, type of medical insurance, prior medication, prior hospitalization for similar problems and the proportion of patients

with various types of symptoms and complications will be compared between the two devices using the exact Chi-square test. Frequency of both superficial and deep suctioning will be compared for the two devices using the Wilcoxon Rank Sum test while patient age (in months) will be compared using Student's t test. Finally, multiple linear regression will be used to examine the association between these covariates and the length of stay, and the potential interaction of these variables with the type of nasal suction device used. All data analysis will be performed using SAS 9.3. A 5% significance level will be maintained for all hypothesis tests.

Section H: Potential Risks/DiscomfortsH1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

This study carries a small risk of potential compromise of patient confidentiality. All patients will be consented prior to enrolling in the study. Once enrolled in the study, patient will be given a unique identification (ID) number (coded) and the link between this number and patient's information will be kept in a separate file. The access to this file will be limited to the PI and co-PI. This will prevent compromise of patient confidentiality. There is minimal risk or discomfort associated with both these devices. The NoseFrida does not go into the nostril far enough so it is less likely to cause any kind of trauma(bleeding, rebound swelling). This device is already in use as a nasal aspirator available over the counter product recommended for suction of babies with nasal congestion. The neosucker however fully enters the nare and commonly causes bleeding, rebound swelling and trauma. The neosucker is the current standard of care for patients with bronchiolitis admitted to the hospital for respiratory distress and poor feeding. Our study seeks to compare the efficacy of this device with the hospital-based standard of care.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

Information obtained from the study will likely benefit the population from which the subjects were drawn. It is anticipated that the use of this device would increase parental satisfaction and involvement in patient care.

Describe potential benefit(s) to society of the planned work.

Information obtained from the study will likely benefit the population from which the subjects were drawn. While NoseFrida can be used by the parents, the NeoSucker can only be used by a healthcare professional. We anticipate that the use of a parent-controlled nasal suction device will decrease the use of limited healthcare resources for nasal suctioning, it will reduce Emergency Department visits, and potentially decrease length of stay in the hospital.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

We anticipate the benefits of the study device to positively impact factors like parental confidence in caring for children with bronchiolitis, length of stay, and number of Emergency Department visits. The risk of using this device are minimal compared to the potential benefits.

Section J: Consent ProceduresJ1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

No

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

No

J2. Consent Procedures

Who will recruit subjects for this study?

PI

PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Patients will be identified based on the inclusion criteria. Consent will be obtained from identified patients. A study packet (consent form, inclusion and exclusion criteria and data collection tool) will be then initiated and completed by the Research Coordinator. This study packet will remain with the patients chart until disposition, when they are to be collected and stored in a password protected computer. Upon enrollment, the study patients will be randomized to nasal suctioning by either the NoseFrida or the NeoSucker suction catheter device. The PLAN procedure in SAS version 9.3 (SAS Institute., Cary, NC) will be used to randomize subjects to one of the two devices. Block randomization will be used with a block size of four to ensure that a similar number of subjects are assigned to each device. The study statistician will generate the randomization sequence before

study enrollment begins. Sequentially numbered sealed envelopes will contain the device to which the patient is randomized. Only after the patient has been consented and enrolled into the study will the envelope be opened to reveal the device to which the patient has been randomized. For patients randomized to the NoseFrida, the Research Coordinator will provide a video demonstration of NoseFrida use and give an instructional post card to the parent/guardian. Both video and postcard will be available in English or Spanish. Parents will then re-demonstrate appropriate use of the device. If at any time deep suctioning is necessary the nurse will perform as reflective of our current standard of care. If at any time overnight the patient requires nasopharyngeal suctioning and the parent/guardian are asleep, the nurse will suction with the NeoSucker (current standard of care). We will review patient records following discharge from Texas Children's Hospital in order to determine return visits. Data will be collected on a data collection tool. A copy of which is attached to this IRB protocol. Once data points are collected, data will be stored in a computer which will be only be accessed by the Research Coordinator, PI and the co-investigators. Following completion of the database, statistical analysis will be performed.

Are foreign language consent forms required for this protocol?

Yes

Which of the following ways will you document informed consent in languages other than English?

Short-Form consent documents

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

Yes

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?

No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?

Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

No

Specific information concerning drug abuse:

No

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

No

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

No

Partial Social Security # (Last four digits):

No

Billing or financial records:

No

Photographs, videotapes, and/or audiotapes of you:

No

Other:

No

At what institution will the physical research data be kept?

At the Pediatric Emergency Research offices.

How will such physical research data be secured?

Locked at all times

At what institution will the electronic research data be kept?

Texas Children's Hospital

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):

No

Such electronic research data will be secured via Other:

Yes, (describe below):

Secure servers identified by Institution/owner.

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

No

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

De-identified data will be shared through secure e-mail

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

None

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

NoseFrida device will be provided by the company free of cost to participants of study. Subjects insurance will be responsible for normal standard of care costs (NeoSucker) but will not be responsible for the research costs.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

0

Distribution Plan:

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug that is not approved by the FDA?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

Yes

[Device 1: NoseFrida](#) [Section Q: Consent Form\(s\)](#)

Consent to participate in study

Section R: Advertisements

None